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SUBJECT: POSITIVE IPR DEVELOPMENTS IN EGYPT

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1. (SBU) Minister of Health and Population Hatem El Gabaly issued an order directing an Egyptian pharmaceutical company to cease production of a generic copy of Lilly's innovator drug Zyprexa. Marketing approval for the generic drug Olapex had been granted to Apex Pharma in December 2005 by El Gabaly's predecessor and the generic has been available locally since January. The order requires Apex Pharma to suspend sales of Olapex pending the outcome of its legal challenge to Lilly's exclusive marketing rights for Zyprexa. These exclusive marketing rights expire August 7, 2006. If the court rules against Lilly prior to August 7, then the order stipulates that Apex Pharma will be permitted to resume sales of Olapex indefinitely. If the court does not make a ruling, or rules in favor of Lilly before August 7, then Alpha Pharma will be prohibited from selling Olapex until Lilly's rights expire on August 7. The only way Alpha Pharma will be prevented from selling Olapex after August 7 is for the Egyptian Patent Office (EPO) to approve Lilly's patent application for Zyprexa before the expiration of Lilly's exclusive marketing rights or an unfavorable court ruling. If the EPO grants a timely patent for Lilly, then Apex Pharma will be prohibited from resuming sales of Olapex until the expiration of Lilly's patent in 20 years. If the EPO does not approve Lilly's patent application by August 7, then the restraining order on Alpha Pharma sales of Olapex will be lifted.

2. (SBU) Ayman Hassenein, Egypt Director for Eli Lilly, recently met with the EPO to ascertain the status of its pending patent application for Zyprexa. According to Hassenein, the EPO is in the final stages of the approval process. One of the last steps is for the EPO to send the Ministry of Health and Population a letter stating that a patent will be issued for Zyprexa at the end of 90 days unless the Ministry responds with a formal objection. According to the head of USAID's IPRA project, the Ministry can respond any time during the 90-day period with either an objection or no objection to the patent. After that, a notice is published in the Patent Gazette stating the EPO's intention to issue a patent if there is no opposition from another rights holder to the product to be patented. According to EPO contacts, there are four pharmaceutical patent applications in the final stages. Once granted, these pharmaceutical patents will be the first issued in Egypt under the WTO TRIPS mailbox procedure. As for Zyprexa, if these final steps are completed before the expiration of Lilly's exclusive marketing rights on August 7, Lilly will have an inviolable patent for Zyprexa in Egypt.

3. (SBU) Although the window of opportunity to get patent protection for Zyprexa is narrow, Lilly's representative here is extremely pleased with the Minister's order. He praised Minister El Gabaly for trying to rectify a bad decision made by his predecessor, who ignored Egyptian legal procedures by issuing a marketing approval for a Zyprexa generic while the legal challenge to Lilly's exclusive marketing rights was still pending. Minister El Gabaly's decision, said Hassenein, at least revives the possibility of patent protection for Zyprexa in Egypt, which was dashed when the marketing approval for Olapex was issued last December. Moreover, said Hassenein, Lilly's lawyers are investigating the option of challenging Apex Pharma's right to sell Olapex after August 7 should its patent for Zyprexa not be issued by then.

4. (SBU) The GOE's interest in stronger IPR protection has been quite evident of late. During a recent public appearance, El Gabaly promised to meet all of Egypt's IPR obligations under WTO, and Minister of Trade and Industry Rachid has been making numerous public statements about creating a positive IPR environment in Egypt. Minister Rachid has also taken concrete steps to promote his vision, the latest being his hiring of a respected IPR attorney (and former USAID IPRA project employee) to be head of the Trademark Office. Another positive step is a request made to the USAID IPRA project by the Minister's deputy for a list of specific steps the GOE could take to improve IPR protection in Egypt. The stated goal was to get Egypt off the Special 301 Priority Watch List.

15. (SBU) Comment: Minister El Gabaly's decision on Zyprexa is welcome, as are Minister Rachid's public support and concrete steps for stronger IPR protection in Egypt. We suspect that Minister Rachid will be more proactive in promoting IPR protection than Minister El Gabaly, who readily acknowledges the indispensable role inexpensive generic drugs play in Egypt's health care system. While we may not see seismic changes in Egypt's IPR regime in the near term, Egypt's economic reformers recognize the benefits of stronger IPR protection are moving toward that goal. End comment.
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